

UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

IN RE: NEW ENGLAND COMPOUNDING
PHARMACY, INC. PRODUCTS LIABILITY
LITIGATION

MDL No. 2419
Master Dkt. 1:13-md-02419-FDS

THIS DOCUMENT RELATES TO:

Judge Rya Zobel

All Cases Identified In Dkt. Nos. 1401, 1471,
1472, & 1473 and The PSC's Previous
Response Dkt. No. 1518 & 1519.

**THE PLAINTIFFS' STEERING COMMITTEE'S SUPPLEMENTAL RESPONSE TO
LIBERTY INDUSTRIES INC.'S OMNIBUS MOTION FOR SUMMARY JUDGMENT IN
CASES FILED BY PLAINTIFFS INJECTED IN INDIANA**

I. INTRODUCTION

During last week's status conference, the Court asked the Plaintiffs' Steering Committee ("PSC") what additional discovery is needed with regards to its claims against Liberty Industries, Inc ("Liberty").¹ The PSC hereby responds.

The PSC needs the following additional discovery to best oppose Liberty's summary judgment motions:

- Depositions of Liberty owners/employees George Pollick, John Nappi, Jr., and Jay Schneider to address the following topics ([REDACTED])
 - (1) the design of the 2005 cleanroom,
 - (2) the addition of the passthrough to the 2006 cleanroom, and
 - (3) the decision not to add a secondary ceiling to the 2006 cleanroom;
- Discovery from NECC and/or the Insiders confirming
 - (1) that the contaminated MPA was compounded in the 2006 cleanroom designed and built by Liberty,
 - (2) Liberty's representations to NECC about intended use of its cleanrooms, and
 - (3) whether NECC significantly modified the Liberty built cleanrooms; and
- Expert Discovery about Liberty's failure to properly design and construct the cleanrooms, based on Liberty's deposition testimony and the requested additional discovery.

All of the documents produced by Liberty to date deal specifically with the three clean rooms Liberty designed and built for NECC. A second set of narrow and pointed document requests would further bolster the summary judgment record as to Liberty's standard procedures for cleanroom design and construction, internal memos on topics such as aseptic processing and USP <797>, documents pertaining to other cleanrooms built by Liberty for aseptic processing, and marketing materials. These documents will provide evidence necessary to support elements

¹ See generally December 4, 2014 Hearing Transcript.

of the PSC's claims such as duty and breach which Liberty currently challenges in its motions.

Accordingly, for reasons set for in this briefing, the PSC continues to seek relief under Federal Rule of Civil Procedure 56(d). Alternatively, if the Court decides not to order that the time to respond to Liberty's motion be deferred under 56(d), the PSC seeks leave to file a substantive response to Liberty's Motions for Summary Judgment; any such substantive response would be filed expeditiously.

II. PROCEDURAL HISTORY

The procedural history of discovery against Liberty Industries is helpful to understand that despite Liberty's concerns with how discovery is progressing, the PSC has rapidly pursued discovery against Liberty. The history further illustrates how premature Liberty's motions are, and why the PSC responded under Rule 56(d).

A. The PSC's efforts to take discovery from Liberty and the Insiders.

Formal discovery has been stayed for most of this MDL's existence. The PSC has fought to lift discovery stays at various points.² It is only recently, with the Court's Orders addressing Common Discovery (MDL Order No. 9, Dkt. No. 1425, Sept. 18, 2014) and Limiting Discovery and Staying These Proceedings with Respect to NECC Insiders and Related Settling Parties (Dkt. No. 1482, Oct. 9, 2014), that formal discovery has begun.

Liberty filed its Motion for Summary Judgment in the Lambert case on September 11, 2014, before the PSC had an opportunity to take any formal discovery relating to Liberty.³

One week later, on September 18, 2014, this Court issued MDL Order No. 9 titled Order

² Plaintiffs' Steering Committee's ("PSC") Motion to Partially Lift Discovery Stay (Dkt. # 534); Plaintiffs' Steering Committee's Motion for Entry of Bellwether Trial and Pre-Trial Scheduling Order (Dkt. No. 837); PSC's Joinder in Liberty's Motion for 16.1 Conference and Discovery (Dkt. No. 1261).

³ Dkt. No. 1401. Liberty then filed an Omnibus Motion for Summary Judgment in Indiana cases on October 6, 2014. Dkt. Nos. 1471-1473.

Regarding Common Issue Discovery. The Order states, “[N]o depositions may be taken until after 60 days from the date of this Order.”⁴ The PSC noticed depositions of Liberty President Bob Kaiser and Project Engineer Jeffrey Erickson for November 18, 2014, the first possible day that a deposition may occur under MDL Order No. 9.

B. PSC’s response to Liberty’s Summary Judgment Motions.

On October 31, 2014, after an assented to extension on the due date for the Lambert Response, the PSC filed its 56(d) response to both the Lambert and Omnibus Motions.⁵ The PSC asked, “To the extent the Court is not willing to deny the Liberty Motion for Summary Judgment outright, Plaintiffs respectfully request that the Court permit them the opportunity to brief the merits of the motion, or the lack thereof, more fully.”⁶ This filing was 18 days before the depositions of the two Liberty employees.

On November 18, 2014, the PSC deposed both Mr. Kaiser and Mr. Erickson.⁷

Thanks to a tremendous job by the court reporter, the final transcripts for these depositions were received on Monday, November 24, 2014. Under MDL Order No. 10, titled Deposition protocol, Mr. Erickson and Mr. Kaiser have until December 24, 2014 to correct, sign and return the transcript to the deposing party.⁸

On November 25, 2014, the day after receiving the Liberty deposition transcripts, the PSC filed its Motion to Schedule Oral Arguments at the Status Conference on December 4,

⁴ Dkt. No. 1425.

⁵ Dkt. No. 1518.

⁶ *Id.* at p. 16.

⁷ The time for designating those deposition transcripts confidential pursuant to the Third Amended Protective Order has not yet lapsed. As counsel for Liberty has not yet responded to our request to file excerpts of those deposition transcripts publicly, the PSC is filing a motion for leave to seal and a redacted version of the brief and attachments via ECF.

⁸ Dkt. No. 1426. As of the date of this brief, neither deponent has returned the transcript to deposing parties, nor have either indicated waiver of this requirement.

2014.⁹ The PSC did not ask for the Liberty summary judgment motions to be heard. On November 26, 2014, Liberty filed its opposition to the PSC's schedule and filed a motion for oral argument on the PSC's 56(d) response.¹⁰ The Court heard argument on (or at least discussion about) this motion during the December 4, 2014 Status Conference.

C. Discovery from Liberty to date.

The PSC has reviewed at least 9,921 pages of documents produced by Liberty relating to the three cleanrooms that it designed and constructed for NECC and/or Ameridose in 2005, 2006, and 2008. The PSC has also reviewed thousands of pages of documents provided by other defendants in search of information relevant to its case against Liberty.

The PSC has also taken the depositions of two senior and long-time employees at Liberty.

The PSC is working with experts to further develop its case against Liberty and for assistance with fact discovery. MDL Order No. 9 does not contemplate expert disclosures for another six months.

III. ADDITIONAL DISCOVERY NEEDED

The PSC needs the following discovery to further develop its case against Liberty and to adequately respond to Liberty's dispositive motions:

A. Deposition of Liberty owners/employees George Pollick, John Nappi, Jr., and Jay Schneider, to address topics about which the Liberty deponents were not knowledgeable.

The PSC will formally seek depositions of George Pollick, John Nappi, Jr., and Jay Schneider. The roles of these owners and/or employees were described during the November 18, 2014 depositions. Their testimony is necessary to fully understand the role Liberty played in

⁹ Dkt. No. 1563.

¹⁰ Dkt. Nos. 1564-1565.

constructing, certifying, and modifying the three Liberty-built cleanrooms at NECC. Their testimony will also illustrate what information Liberty was aware of when undertaking the designs. This is critical to the duty element of the PSC's claims.

George Pollick [REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]

Mr. Pollick was involved in [REDACTED]
[REDACTED] (a potential source of contamination and violation of USP <797>
which Mr. Erickson testified [REDACTED]

Further, according to Mr. Erickson, Mr. Pollick may have been involved in [REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]

Lastly, Mr. Pollick is likely to possess additional professional knowledge on many of the topics which Mr. Erickson provided testimony; [REDACTED]
[REDACTED]
[REDACTED]

John Nappi, Jr. is the owner of the company and responsible for representations and

¹¹ See Deposition of Jeffrey C. Erickson dated November 18, 2014 ("Erickson Dep. Trans.") pp. 20-21, lines 24-3. All excerpts of the Erickson transcript cited are attached as Exhibit 1.

¹² See Erickson Dep. Trans. p. 156, lines 6-9.

¹³ See Erickson Dep. Trans. pp. 128-129, lines 12-3; p. 179, lines 10-23.

¹⁴ See Erickson Dep. Trans. pp. 154-155, lines 20-15.

¹⁵ See Erickson Dep. Trans. pp. 193-194, lines 7-16.

¹⁶ See Erickson Dep. Trans. p. 206, lines 16-24.

¹⁷ See Erickson Dep. Trans. pp. 205-206, lines 17-2.

marketing decisions made by Liberty to the public. [REDACTED]

[REDACTED]

[REDACTED] As the owner of the company, he is also likely responsible for standard operating procedures and oversight of senior employees at Liberty.

Jay Schneider [REDACTED] [REDACTED]

[REDACTED]

[REDACTED] The PSC was previously unaware that Mr. Erickson was not present at Liberty for the design phase of the first cleanroom at NECC. The design phase for the first cleanroom would be critical for understanding what assumptions carried over into subsequent projects at the NECC facility.

Subject to the amount of questioning from other non-PSC attorneys, the PSC anticipates that all three depositions could be completed on the same day, scheduled at the convenience of the deponents.

B. Discovery from NECC and/or the Insiders confirming (1) that the contaminated MPA was compounded in the 2006 cleanroom designed and built by Liberty, (2) Liberty's representations to NECC about the intended use of its cleanrooms, (3) whether NECC significantly modified the Liberty built cleanrooms.

On October 9, 2014, the Court issued the Order Limiting Discovery and Staying These Proceedings with Respect to NECC Insiders and Related Settling Parties.²¹ Before then, all formal discovery against NECC and the Insiders had been stayed. This recent Order permits discovery against Estate Parties and the Insider Settling Parties "to the extent the discovery is

¹⁸ See Erickson Dep. Trans. p. 26, lines 6-11.

¹⁹ See Erickson Dep. Trans. pp. 21-22, lines 15-4.

²⁰ See Erickson Dep. Trans. pp. 34-35, lines 22-9.

²¹ Dkt. No. 1482.

relevant to the prosecution, or defense, of claims against defendants other than the Estate Parties or the Insider Settling Parties.”²²

Discovery from NECC related personnel is necessary for purposes of confirming what is only currently suspected: that the contaminated MPA was compounded in the 2006 cleanroom designed and built by Liberty. In fact, Liberty’s Motion for Summary Judgment includes a statement under a heading titled “Statement of Undisputed Material Facts” which states, “Although Plaintiffs do not know in which Cleanroom the contaminated MPA was compounded, MPA ingredients were found in the 2006 Cleanroom during an inspection of the Facility in July, 2014.” Just prior to the Court issuing the Order Limiting Discovery and Staying These Proceedings with Respect to NECC Insiders and Related Settling Parties, Liberty themselves stated that discovery of NECC personnel is necessary to determine where the contaminated MPA was compounded.²³

The PSC also seeks discovery from NECC to prove what representations were exchanged between NECC and Liberty regarding the intended use of the cleanrooms. Such information would be relevant to further showing the existence of a duty owed to Plaintiffs in the design and build stages of the cleanroom projects. Liberty claims that it did not breach any duty to any plaintiff.²⁴ Liberty states in its Motions for Summary Judgment that NECC instructed Liberty to proceed with certification of the 2006 cleanroom regardless of the timing being premature. The PSC seeks to discover the circumstances surrounding this allegation as Liberty seeks to shift blame for mishaps onto NECC representatives.

Lastly, the PSC will seek discovery from NECC representatives relating to Liberty’s

²² *Id.*

²³ See Footnote 4, Page 12, Dkt. No. 1472.

²⁴ See Page 1, Dkt. No. 1472.

statements that NECC made significant modifications to the cleanrooms after Liberty completed its work at the facility.²⁵ Similarly, the PSC will seek discovery on the state of the cleanrooms after Liberty left and whether ceiling tiles ever popped, or whether gaps were sealed. This is needed because Liberty argues that “all of the conditions cited in the exhibits to the Master Complaint are alleged to reflect the condition of the Facility at the time of the outbreak in September and October, 2012, not the condition when Liberty completed construction of the 2006 Cleanroom.”²⁶

The PSC intends to work with the Trustee and counsel for the Insiders to obtain formal discovery responses that address all three of these topics in an efficient, but formal way.

C. Expert Discovery as to the proper design and construction for cleanrooms, based on Liberty’s arguments and deposition testimony.

The PSC seeks expert discovery in areas such as proper design and construction for cleanrooms, proper design and construction for USP <797> cleanrooms, proper certification methods for cleanrooms, whether bi-annual air testing of the NECC cleanrooms performed by Scientific Air Analysis was properly performed; whether positive test results in bi-annual air testing performed by Scientific Air Analysis would be dispositive of the issue of whether the cleanroom was properly designed, built, and certified, whether Liberty performed a proper engineering analysis of the NECC facility when designing and constructing its cleanrooms; what designs would have been more appropriate for the NECC facility; and whether cleanrooms should have even been placed inside of NECC’s warehouse.

Experts will be needed as fact discovery progresses especially for purposes of establishing causation. Liberty relies heavily on the premise that satisfactory results of bi-annual

²⁵ See Page 10, Dkt. No. 1472.

²⁶ See Page 10, Dkt. No. 1472.

testing of the cleanrooms show that the cleanrooms were allegedly functioning as required.²⁷

Eventually, full expert report(s) will be produced and Plaintiffs' expert(s) will be available for deposition.

D. A second set of narrow and pointed document requests would further bolster the summary judgment record.

Under the Order Regarding Common Issue Discovery, the PSC is entitled to serve two separate Requests for Production, 50 Requests for Admission, and 40 Interrogatories.

The PSC currently intends to serve a second set of narrow document requests to probe issues raised during the Erickson and Kaiser depositions. All of the documents which Liberty has produced relate to "the three cleanrooms that it designed and constructed for New England Compounding Pharmacy."²⁸ The PSC believes that other information such as Liberty's standard procedures for cleanroom design and construction, internal memos on topics such as aseptic processing and USP <797>, documents pertaining to other cleanrooms built by Liberty for aseptic processing, and marketing materials will provide evidence necessary to support elements of the PSC's claims such as duty and breach.

IV. CONCLUSION

Plaintiffs ask the Court to grant their Rule 56(d) request. In the alternative, if the Court decides not to order that time to respond be deferred under 56(d), the PSC renews its request for leave to file a substantive opposition to Liberty's Motions for Summary Judgment;²⁹ any such substantive opposition would be filed expeditiously and in accordance with the Court's order.

²⁷ See Page 7, Dkt. No. 1472.

²⁸ See Dorman Affidavit, Dkt. No. 1544-1, attached as Exhibit 2.

²⁹ Dkt. No. 1518 at p. 16 ("To the extent the Court is not willing to deny the Liberty Motion for Summary Judgment outright, Plaintiffs respectfully request that the Court permit them the opportunity to brief the merits of the motion, or the lack thereof, more fully.").

Dated: December 9, 2014

Respectfully submitted,

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CERTIFICATE OF SERVICE

The undersigned hereby certifies that on December 9, 2014, a true and exact copy of the foregoing was filed with this the Clerk of the Court using the ECF system that sent a notification of this filing to all ECF registered counsel of record via e-mail generated by the Court's ECF system.

/s/ Kristen A. Johnson

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